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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER MORAN, MARJORIE A	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/960,706

Applicant(s)

MUNGER ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-31, 39-52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-38 and 54 is/are rejected.
- 7) ☒ Claim(s) 33-38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### ***Election/Restrictions***

Applicant's election of Group VI, claims 32-38 and 53 in a response filed 10/15/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-31, 39-52 and 54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 10/15/03.

An action on the merits of elected claims 32-38 and 53 follows.

### ***Information Disclosure Statement***

It is noted that two IDS's have been filed, on 6/11/02 and 8/21/02. Unfortunately, the references cited in both IDS's appear to have been lost in converting from a paper file to electronic file. The examiner regrets the inconvenience and requests that applicant submit another copy of each non-patent reference. The date of filing of any reference previously cited will be considered the date of filing of the original IDS.

### ***Specification***

The abstract of the disclosure is objected to because it is not directed to the subject matter of the elected claims. Appropriate correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: The priority information is incorrectly stated on page 1 of the specification. The statement should be amended to state that the present application claims *priority to* the US application and *benefit of* the provisional application. Appropriate correction is required.

### ***Claim Objections***

Claims 33-38 are objected to because of the following informalities: each dependent claim should begin with --The--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup>***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-38 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK OF WRITTEN DESCRIPTION rejection.

A computer system comprising a database containing information identifying the expression level of ANY set of genes, specifically those in Tables 1-6, is not described.

Tables 1-4 and 6 contain lists of "Affimatrix elements" identified by SEQ ID NO: and associated with a Genbank ID number and name. It is not known or disclosed whether the "Affimatrix element" exactly corresponds to the SEQ ID NO: (i.e. does an "element" correspond to more than a single SEQ ID NO?). Nor does the specification disclose whether the Affimatrix element/SEQ ID NO: exactly corresponds to the sequence found in Genbank, corresponds to a fragment of the Genbank sequence, or simply has some degree of homology to the Genbank sequence. It is not disclosed which, if any, of the sequences listed in a Table is known to be a gene. It is noted, for example, that many of the sequences are identified by Genbank as "ESTs" or as cDNAs or proteins. None of these are genes. A search in Genbank of several of the sequences chosen at random from Table 1 indicates that sequences are NOT identified as, or with, any gene. Genbank accession number S77622 is a sequence of only 23 nucleotides, and appears to encode a portion of an antibody. It is highly unlikely that this sequence represents a gene. The Genbank record for R93908 is a cDNA sequence isolated from a liver/spleen library. Similarly, The Genbank record for N30198 is a cDNA sequence isolated from placental tissue. A cDNA is, by definition, not genomic. Table 6 specifically identifies the sequences listed therein as fragments (Affimatrix Fragment Name). One skilled in the art does not generally define a gene as a sequence "fragment".

Table 5 identified its sequences only by cluster and "fragment name". The sequences are not identified by SEQ ID NO. A cursory review of the Tables does not find any clear correlation between the "fragment names" of table 5 and any SEQ ID NO: or Genbank identifier, such that one skilled in the art would be able to determine

whether the "fragments" of Table 5 correlate in any way to a gene. AS set forth above, one skilled in the art does not normally define a gene as a sequence "fragment".

The specification repeatedly refers to the "genes" of Tables 1-6, but does not actually identify any gene anywhere, nor make any correlation between a sequence disclosed in any Table and a particular gene.

A database containing information identifying the expression level of any sequence (gene or otherwise) in BPH tissue or cells, or normal or cancerous tissue or cells, is not described anywhere. Tables 1-5 merely indicate sequences which are up-regulated or down-regulated in BPH as compared to another tissue; these Tables do not indicate actual expression LEVELS of the listed sequences in BPH tissue or cells, or the comparative tissue or cells, anywhere. A disclosure that "more" or "less" of a gene product (protein, mRNA or cDNA) is found in a particular tissue relative to another tissue is not a disclosure for an actual "level" of expression of a sequence in a single tissue. Table 6 does disclose actual numbers, but these are not expression levels or amounts, but are p-values, again showing a comparison between tissues. Figures 1-6 show expression "levels", but in all cases, these are indicated as being "Relative" levels. Also, it is unclear which of the sequences, if any, from the Tables is indicated in the Figures. A cursory review of the Tables does not show a correlation between the "identifiers" of the Figures and the sequences of the Tables. Further, the Figures are not "databases", therefore the "Relative Expression Levels" of the Figures do not

appear to be a description of a computer system comprising a database containing expression levels of genes listed in Tables 1-6.

As a database comprising neither expression information for sequence known to be genes nor actual expression levels for sequences in the database are fully and completely described by the instant specification, the claims are rejected for lack of written description.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup>***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-38 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites a "set of genes" in line 3. However, as no sequence in the disclosed Tables is known to be a gene, it is unclear what sequences are intended by applicant, and the claim is indefinite. Further, as Table 5 does not identify any sequence by SEQ ID NO, one skilled in the art would not know what nucleic acid sequences are intended by applicant in Table 5, and the claim is further indefinite.

Claim 33 specifically recites genes from Table 5. For the same reasons as those set forth above, claim 33 is also indefinite.

Claim 37 limits the database of claim 32 to comprise records including "descriptive information". It is unclear what the information is intended to describe, therefore the claim is indefinite.

Claim 53 limits a gene expression level to be "detected by" a bDNA method. This appears to be a method step; however, parent claim 38 is directed to a computer system (product). As it is unclear what limitation of the product is intended by the apparent method step, claim 53 is indefinite.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-38 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over MASLYN et al. (US 5,953,727)

MASLYN teaches a computer system comprising relational sequence information and a user interface (col. 2). It is noted that as the sequence and expression level information recited in the claims do not have a functional relationship with the hardware recited in the claims, they do not distinguish the invention from the prior art in terms of patentability. The sequences and associated information are nonfunctional descriptive matter (see MPEP 2106), and do not *functionally* interact with any hardware or software in the claimed methods. The claimed methods therefore may be performed using any set of sequences/expression information. As set forth in *In re Gulack*, 703 F. 2d 1381 (217 USPQ 403,404), when there is no functional relationship between matter which is, by itself, non-statutory subject matter and a substrate (e.g. a computer), there is no reason to give patentable weight to the content (of the non-statutory subject matter). The sequences/expression levels recited in the claims do not therefore distinguish the claimed method from the prior art in terms of patentability, and the claims are obvious.

### **Conclusion**

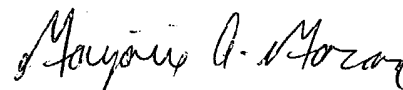
Claims 32-38 and 53 are rejected; claims 33-38 are also objected to. The specification is objected to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0549.



Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

mam